

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Robert J. Marshall

Serial No: 10/722,777

Filing Date: 26 November 2003

Customer No. 51079

Title: **STABILIZED DIHYDROLIPOIC ACID
AND METHOD OF PRODUCING SAME**

Group No: 1651

Examiner: Thane E. Underdahl

Confirmation No.: 7232

DECLARATION UNDER RULE 37 CFR §1.132

I, Robert J. Marshall, declare as follows:

1. I obtained a B.S. degree in Chemistry and Mathematics from the University of Dayton in 1963, a M.S. degree in Operations Research from Purdue University in 1965, and a PhD degree in Holistic Health Science at from Columbia Pacific University in 1978. In 1991, I received certification as a clinical nutritionist through the International and American Association of Clinical Nutritionists ("IAACN") under the sponsorship of the Clinical Nutrition Certification Board.

2. Since 1974, I have worked continuously in the field of clinical nutrition and nutrition research. I was a clinical nutrition instructor at the California Acupuncture College (1980-1982), the Cleveland Chiropractic College (1986-1987), and for IAACN (1993-1997).

3. I have authored numerous publications which are detailed in my Curriculum Vitae, a copy of which is attached. Since 1984, I have lectured on the topics of nutrition, health, and the use of dietary supplements which are also detailed in my Curriculum Vitae.

4. Since 1983, I have been involved in and have actual experience in formulating, testing and manufacturing dietary supplements.

5. I am the inventor of and have read and understand U.S. Patent Application Serial No. 10/722,777 ("Marshall application"). I have also read and understand U.S. Patent 6,368,617 to Hastings et al. ("Hastings"), "Enantioselective pharmacokinetics and bioavailability of different racemic α -lipoic acid formulations in healthy volunteers," European Journal of Pharmaceutical Sciences, 4 (1996) 167-174 by Hermann et al. ("Hermann"), "Pyruvate Dehydrogenase & Krebs Cycle," by Joyce J. Diwan (1998) ("Diwan"), "A Trail of Research from Lipoic Acid to α -Keto Acid Dehydrogenase Complexes," Journal of Biological Chemistry, Vol. 276, No. 42, Oct. 19, 2001, 38329-38336 by Lester J. Reed ("Reed"), and U.S. Patent No. 6,080,401 by Reddy et al. ("Reddy").

6. I believe that Claims 4-12, 20-22, and 24 of the Marshall application are directed to an important and patentable improvement over the subject matter described in Hastings, Hermann, Diwan, Reed, and Reddy.

7. I have reviewed the Office Action for the United States Patent and Trademark Office dated November 24, 2008 in my application. I noted the following statements:

Page 4, lines 9-13 of the Office Action:

"Compositions are limited by their structure and not their intended uses such as a "microbiological culture media". However, the prior art cited by the Examiner teaches it would be obvious to one of ordinary skill in the art to make a composition with the same structural components of the instant compositions. Therefore any inherent property of such a compositions [sic] is also obvious."

Page 5, lines 4-8 of the Office Action:

"Even though the prior art composition is not specifically taught as being useful for Applicant's claimed intended use or application, i.e., microbiological culture medium, it obviates the currently claimed invention, absent a substantive showing that the prior art could not be employed for the instantly claimed invention."

Page 5, lines 17-21 of the Office Action:

“In summary, since the prior art previously cited teach all the components of the composition as claimed that are obvious regardless of the intended use of the composition. This rejection can be overturned if evidence is provided that shows the composition cited by the Examiner could not be used for the same purpose...”

8. The compositions of Hastings and Reddy rely in part on the activity of probiotic organisms to achieve their objective, i.e., to provide a beneficial therapeutic effect to a user of the composition.

9. I am unaware of a nutritional or dietary supplement which includes a probiotic organism for providing a beneficial therapeutic effect which also contains an agent known to halt probiotic activity, as it is such biological activity which is believed to provide the beneficial therapeutic effect. It is my opinion that one of ordinary skill in the art of preparing nutritional and dietary supplements would seek to avoid the inclusion of an agent to halt probiotic activity in compositions such as those disclosed in Hastings and Reddy.

10. Supplement compositions such as the ones identified in Hastings and Reddy were at the time of my invention and still today are generally mixed, combined, prepared and/or manufactured at approximately room temperature, i.e. about 20°C to 25°C.

11. Based on my knowledge of and experience with dietary supplements and probiotic organisms, I have found, and one of skill in the art would have recognized, at the time of the invention, that probiotic organisms are active at temperatures at or above room temperature and thus could consume any available food. However, when such a food supply is exhausted cell death occurs.


12. As is well known in the art, dietary supplements containing live probiotic organisms are handled and stored at temperatures below about 20°C in order to preserve the activity of the probiotic organisms.

13. Optimum growth temperatures for most probiotic organisms fall in a range between 37°C and 43°C. Generally, little or no growth is observed for most *Bifidobacterium* and *Lactobacillus* species below 20°C and above 46°C.

14. Based on my knowledge of and experience with microbiological culture media and numerous experiments conducted in the course of development of the claimed microbiological media, I have found that the activity of probiotic organisms in a microbiological media including at least one nutritive agent is diminished at room temperatures.

15. It is my belief that one of skill in the art would not expect a microbiological culture media to produce appreciable amounts of any compound absent incubation at elevated temperatures or incubation for extended periods of time.

I acknowledge that willful and false statements are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and may jeopardize the validity of this Marshall application or any patent issuing from it. I declare under penalty of perjury under the laws of the United States that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.


Robert J. Marshall


Date

Curriculum Vitae

Name: Robert J. Marshall, PhD, CCN, DACBN

Current Position: CEO, Premier Research Labs

Address: 3500 Wadley Pl., Building B
Austin, TX 78728

Education

Institution

University of Dayton (Dayton, OH)
Purdue University (LaFayette, IN)
Columbia Pacific University (Mill Valley, CA)

Degree

B.S. (1963)
M.S. (1965)
PhD (1978)

Professional Occupation

Clinical Nutritionist in multi-disciplinary private practice 1974 – present

Teaching Positions

Dates

Instructor, Clinical Nutrition	
Cleveland Chiropractic College (Los Angeles, CA)	1986-87
Clinical Nutrition Instructor	
California Acupuncture College (Westwood, CA)	1980-82
Clinical Nutrition Instructor (Los Angeles, CA)	1993-97
IAACN ((International and American Association of Clinical Nutritionists)	

Memberships, Organization Positions

Member, American Society of Tropical Medicine and Hygiene	1980 - present
Member, IAACN (International and American Association of Clinical Nutritionists)	1991 - present
Awarded credential: CCN (Certified Clinical Nutritionist), 1991	
Past President, IAACN (International and American Association of Clinical Nutritionists)	1998 – 2000
Member, Council on Nutrition (American Chiropractic Association)	2005 - present
Awarded credential: DACBN (Diplomate of the American Clinical Board of Nutrition), 2005	

Lecturer and Presenter

Highlights

QRA™ (<i>Quantum Reflex Analysis™</i>), Level I (Basic)	2000 –present
A Professional Practitioner Seminar	
Seminar Director and Presenter, various U.S. cities	
QRA™ (<i>Quantum Reflex Analysis™</i>) Level II (Advanced)	2000 –present
Seminar Director and Presenter, Austin, TX	
Lecturer, Instructor on Various Health-Related Topics at various professional Conventions, Seminars	1984 - present
Presenter, IAACN Symposium (International and American Association of Clinical Nutritionists), a prestigious organization for certification and advancement of clinical nutritionists	August, 1999
Topic, “Degeneration and Regeneration in a Toxic World”	
Presenter, various lectures at ANMA (American Naturopathic Medical Association), a national naturopathic organization for certification and advancement of naturopathy	2000 - 2003

Presenter, Natural Healthlink (a prestigious, multi-discipline organization promoting integrative medicine)	2000 - 2002
Presenter of various topics: Natural Healthcare in Integrative Medicine, Nutrient Showcase, Meridian Stress Analysis, etc.	

Media Outreach

<u>Host</u> , HealthLine Radio Show	1986 - present
Daily Health Talk show (Currently in 85 markets in US)	
<u>Media Appearances</u>	
Guest speaker and guest appearances on various radio & TV shows	1976 - present

Research and Development Accomplishments

International Patent-Pending (#10/722,777): Production and Use Patent for the stabilization of DHLA (Dihydrolipoic acid) for dietary use (2004)

Co-Developer and Inventor (2000-2004)

QRA™ (Quantum Reflex Analysis™), a unique system that tests the hierarchy of the body's reflexes and interference fields for advanced healing and elimination of chronic pain/disease conditions

Publications and Articles

Author, "The Overlooked Role of Chronic Infection in Neurodegeneration and Its Reversal Using Nutraceutical Agents: Part One", *Nutritional Perspectives: Journal of the Council on Nutrition*; Vol 27, No.2, April, 2004, p.5-18.

"The Overlooked Role of Chronic Infection in Neurodegeneration and Its Reversal Using Nutraceutical Agents: Part Two", *Nutritional Perspectives: Journal of the Council on Nutrition*; Vol 27, No.3, July, 2004, p.7-18, 30-31.

Author, "Basic Dietary Practices Handbook" (1976)

Co-Author, "Nutrition, Health and Activity Profile (a computerized health-teaching tool for practitioners) (1977)

Co-Author of the following research and health-related publications and monographs

The Complete QRA™ (*Quantum Reflex Analysis*™) Manual, Level I (400+ pages) for Practitioners and Healthcare Providers (2004)

QRA™ (*Quantum Reflex Analysis*™) Manual, Level II (300+ pages) for Practitioners and Healthcare Providers (2005)

"Leaky Gut Syndrome: How Toxic Intestines Create Far-reaching Health Problems"

"Adrenal Stress Index: Evaluating Adrenal Function Through Cortisol and DHEA"

"Benzene: How Solvents Contaminate Foods and Personal Care Products"

"Alzheimer's Disease: The Close Link to Digestion"

"Detoxification: Understanding the Healing Process"

"Calcium Metabolism: Key Factors to Preserve Bone"

"The Toxic Effects of Highly Heated Foods"

"Ten Secrets for a Healthy, Long Life"

"Essential Step to Feel Your Best: Adopting a Healthy Lifestyle"

"Toxic Teeth: the Hazards of Silver Fillings and Other Dental Materials"

"Power Food Habits: Lifelong Dietary Habits for Outstanding Health"

"Overcoming Candida"

"Creating Natural Light Indoors: Using Color-corrected light bulbs"

"Getting Off Coffee the Easy Way"

"MSG: The Hidden Poison in your Food"

"Osteoporosis: The Major Causes, How to Avoid and Reverse Them"

"Parasites: The Hidden Epidemic"

"Understanding PMS and Menopause"

"Water: The Healing Properties of Pure Water"

"Allergies: Breakthrough Nutritional Help"

"The Back Pain Solution"

“The Complaining Patient: Steps to Overcome Anger and Self Pity”
“Constipation: Death Begins in the Colon”
“Cultured Drinks: How to Make Your Own”
“Drug Side Effects: How Drug Side Effects Can Delay Healing”
“The Powerful Role of Digestive Enzymes”
“Essential Fatty Acids with End Chain Product Summary”
“The Estrogen-Cancer Connection”
“Hysterectomy: Dangers vs. Healthy Alternatives”
“Insomnia: The Sleepless Despair”
“Oils: Their Types and Functions”
“Pesticides: The Devil’s Holy Water Cursing Our Crops”
“The Amazing Effects of Essential Oils”
“Weight Loss: 10-Day Program to Aid Weight Loss”
“Toxic Electromagnetic Fields: You Need Protection”
“Recipes for a Healthy Lifestyle”